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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,431	03/16/2000	JOHN W WONG	287300022USA	7974

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT PAPER NUMBER

3761

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/424,431

Applicant(s)

WONG, JOHN W

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-10,12,14,15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-10,12,14,15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, 3, 4, 6-10, 12, 14, 15, and 17-22 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 4 and 12 are dependant claims that depend on cancelled claims.

Claim Rejections - 35 USC § 103

5. Claims 1, 3, 4, 6, 7, 9, 10, 12, 14, 15, and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rienmueller et al. in view of Nord 5,915,381.
6. As to claim 1, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation, the method comprising the steps of: identifying a specific air flow direction and lung volume (col. 2, lines 3-4); suspending patient ventilation at a specific air flow direction and lung volume (col. 2, lines 12-19, and col. 3, lines 40-45); and administering radiation therapy during the suspension of patient ventilation (col. 1, lines 63-65). It should be noted that Rienmueller et al. fails to teach a ventilator assembly having a first selectively operable valve adapted to control inhalation of the patient and a second selectively operable valve adapted to control

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exhalation of the patient. However, Nord does teach a ventilator assembly (fig. 1) having a first selectively operable valve 10 adapted to control inhalation of the patient and a second selectively operable valve 20 adapted to control exhalation of the patient. Therefore it would have been obvious to one of ordinary skill in the art to include the method step of using a ventilator comprising a first and a second valve to control/aid the ventilation of a damaged or diseased lung. Furthermore, Rienmueller et al. discloses the claimed invention except for a ventilator assembly having a first and a second valve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a first and a second valve, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

7. As to claim 3, Rienmueller/Nord teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method including the step of utilizing a computer control to provide a measure of the cyclical expiration and inhalation cycle of the patient (col. 3, lines 14-16).

8. As to claim 4, Rienmueller/Nord teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 2, the method including the step of closing the first and the second selectively operable valves to suspend the patient's breathing at a desired point (col. 2, lines 12-19, and col. 3, lines 40-45).

9. As to claim 6, Rienmueller/Nord teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method

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including repeating the stop of suspending patient ventilation at a specific air flow direction and lung volume as necessary to administer repeated radiation doses (col. 1, line 26-35).

10. As to claim 7, Rienmueller/Nord teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method including undertaking CT planning and treatment at a reproducible ventilatory phase (col. 1, lines 26-35).

11. As to claim 9, Rienmueller/Nord teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method including the steps of acquiring CT scans at different respiratory phases (col. 1, lines 26-35).

12. As to claim 10, Rienmueller/Nord teaches a method for establishing breath-holding reproducibility in a patient for the delivery of radiation therapy, the method comprising the steps of: identifying a lung volume (col.2 lines 8-9); suspending patient ventilation at a lung volume (col. 2, lines 12-19, and col. 3, lines 40-45) utilizing an apparatus comprising a ventilator assembly having a first selectively operable valve 10 adapted to control inhalation of the patient and a second selectively operable valve 20 adapted to control exhalation of the patient; and administering radiation therapy during the suspension of patient ventilation (col.1, lines 63-65).

13. As to claim 12, Rienmueller/Nord teaches a method for establishing breath-holding reproducibility in a patient for the delivery of radiation therapy according to claim 11, the method including the step of closing the first and the second selectively operable

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valves to suspend the patient's breathing at a desired point (col. 2, lines 12-19, and col. 3, lines 40-45).

14. As to claim 15, Rienmueller/Nord teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation, the apparatus comprising: an apparatus for identifying a specific air flow direction and lung volume of the patient 8; an apparatus for suspending patient ventilation at a specific air flow direction and lung volume 14, the apparatus for suspending patient ventilation including a ventilator assembly having a first selectively operable valve 10 to control inhalation of the patient and a second selectively operable valve 20 adapted to control exhalation of the patient; and an apparatus for administering radiation therapy during the suspension of patient ventilation 1.

15. As to claim 21, Rienmueller/Nord teaches an apparatus for suspending ventilation of claim 15, wherein the first 16 and the second 24 selectively operable valves are adapted to operate independent of each other (col. 2, lines 51- 53, and col. 2 lines, 63-65).

16. As to claim 22, Rienmueller/Nord teaches an apparatus for suspending ventilation in a patient for the deliver of radiation therapy to the patient, the apparatus comprising; a ventilator assembly comprising first 10 and second 20 valves, the first valve adapted to control inhalation of the patient and the second valve adapted to control exhalation of the patient; a mouthpiece 9 having a first passage adapted to be placed in a mouth of the patent, a second passage operably connected to the first valve, and a third passage operably connect the second valve, and a pneumotach 28; and a

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computer 12 controllably connect to the first valve, the second valve, and the pneumotach, wherein the computer determines air flow and lung volume measurements of the patient via the pneumotach; and wherein the computer selectively closes the first and the second valves to suspend ventilation of the patient at a desired one of the measurements (col. 2, lines 12-19, and col. 3, lines 40-45).

17. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rienmueller et al. in view of Nord in further view of Donaldson et al. 5,950,631.

18. As to claim 8, Rienmueller/Nord teaches the method for delivery radiation therapy to a patient during suspended ventilation according to claim 1. It should be noted that Rienmueller/Nord fails to teach the step of applying to the patient a mechanical device for attachment to the patient's nose for temporarily halting air passage therethrough. However Donaldson et al. does teach the step of applying to the patient a mechanical device for attachment to the patient's nose 70 for temporarily halting air passage therethrough. Therefore it would have been obvious to one of ordinary skill in the art to modify the method of Rienmueller/Nord to include the step of applying to the patient a mechanical device for attachment to the patient's nose to prevent breathing through the nose affecting treatment.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on (703) 308-2702. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



MM
September 16, 2002



Aaron J. Lewis
Primary Examiner